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Modular Bifurcation Endoprosthesis for Treatment of Abdominal Aortic Aneurysms

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Objective
The authors analyzed a single group's experience treating abdominal aortic aneurysms (AAAs) with a new self-expanding, modular, bifurcated device.

Summary Background Data
Successful exclusion of AAAs by prototype devices has led to several controlled clinical trials evaluating prostheses designed and manufactured specifically for this application.

Methods
Sixteen patients (15 males, 1 female) of American Society of Anesthesiologists grade 2 through 4 and average age of 72 years had AAAs (average 57-mm diameter) treated as part of a phase I Food and Drug Administration-approved trial.

Results
All patients were treated successfully with no surgical conversions. No endoleaks or aneurysm enlargement was noted either predischarge by contrast computed tomography or on follow-up at 1 month by duplex ultrasound examination. At 6 months, 12 of 13 patients who were observed for this interval had no endoleaks, whereas one patient (patient 3) showed a small area of extravasation that appeared to arise from the device in an area that was traumatized at the time of deployment. One procedure-related mortality (6%) occurred in a patient who died of septic complications secondary to a gangrenous gallbladder diagnosed 1 day after the procedure. There were no device-related mortalities. Complications included two iliac artery dissections, two groin wound infections, and two transient elevations of serum creatinine. Other significant variables including median procedure length (5 hours), intensive care unit stay (1 day), hospitalization postprocedure (4.5 days), and blood loss (1100 mL) all decreased as the study progressed. Blood replacement in all but three patients was accomplished by autotransfusion or banked-autologous blood replacement. At 6-month follow-up in 13 patients, the maximum diameter of the aneurysm decreased by an average of 5.6 mm (range, 0–15 mm), and the maximal cross-sectional area decreased an average of 20.3% (range, 0–72%).

Conclusions

This study suggests that endovascular prosthesis exclusion of AAAs using a self-expanding modular device may be effective in many patients who are otherwise surgical candidates for repair if further clinical studies confirm these observations.

Exclusion of abdominal aortic aneurysm (AAA) by endovascular prostheses has been accomplished successfully by many investigators since Parodi reported his pioneering work in this area in 1991.[1-8] Initial devices were fabricated by investigators who combined available intraluminal stents and vascular graft materials. Although the majority of device deployments have been performed and followed by variable monitoring mechanisms, preliminary clinical series have reported minimizing interventions, shorter disability and recovery periods, and suggested the potential for shorter, less-costly hospitalization. Initial limitations of prototype devices including limited applicability to the majority of patients and leaks around the device (endoleaks).[3,6,8,9]

Expanding commercial interest in the development of endovascular prostheses has led to the initiation of several controlled clinical trials evaluating devices designed and manufactured specifically for aortic aneurysm exclusion. This study reports our preliminary experience with 16 patients who were treated as part of a phase I feasibility study approved by the Food and Drug Administration to evaluate a new, self-expanding modular bifurcation prosthesis. The clinical evaluation was initiated after extensive preclinical assessment of the device in laboratory models.[10]

METHODS

Nineteen patients were evaluated for inclusion in the study. The majority of the patients entered in the protocol were referred because they were identified as candidates who had lesions amenable to treatment by the available device. Many were also thought to be poor risk candidates for conventional surgery because of associated medical conditions (Table 1). Angiograms were available for evaluation in 10 patients, and contrast computed tomography (CT) images were obtained before all procedures except one, with spiral three-dimensional (3-D) CT reconstruction performed when possible. The majority of patients were chosen based on available angiograms and contrast CT studies, although 10 patients underwent preintervention angiogram and intravascular ultrasound (IVUS) to make a final determination regarding candidacy (Table 2). Eligible patients were both normal and high-risk (American Society of Anesthesiologists [ASA] grades II–IV) surgical candidates.

Table 1. COMORBID FACTORS

	Number of Patients	%
Coronary artery disease or cardiomyopathy	8	50
Chronic pulmonary disease	1	6
Peripheral vascular disease	3	19
Previous stroke	1	6
Renal dysfunction	1	6
Hypertension	3	18
Previous cancer treatment	2	12
Age >80 yr	2	12

The inclusion criteria for this study were that the patient have an AAA greater than 5 cm diameter, or greater than 4 cm with an increase in size by more than 0.5 cm in the past 6 months. Access vessels must have a diameter large enough to accommodate passage of a 21-French delivery catheter for the main body of the device with the contralateral iliofemoral artery being >5 mm in diameter to accommodate passage of a 16-French contralateral limb delivery catheter. A minimum of 1 cm of nonaneurysmal aortic neck distal to the most inferior major renal artery, with a maximum diameter of 26 mm, was required. Patients also were expected to have at least 1 year life expectancy.

Patients were entered into the study after extensive discussion of the procedures with the patient and available family members and completion of a consent form approved by the Food and Drug Administration and the hospital's Institutional Review Board (IRB). Patients also signed consents for conventional surgical procedures in the event that conversion was necessary.

Patient Demographics

Sixteen patients (15 male, 1 female) were treated in this study. Average age was 72 years (range, 62–85 years). Three patients were ASA grade II, 10 were grade

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Table 2. PATIENT DATA IMAGING METHODS

Patient Number	Postprocedure (mo)	Before			During		After			
		Angio	IVUS	CT	Angio	IVUS	Angio	1 mo Duplex	6 mo CT	IVUS
1	10	×	—	×	×	×		×	×	
2	9	×	×	×	×	×		×	×	
3	9	—	—	×	×	×		×	×	
4	8	×	×	×	×	×		×	×	
5	8	×	×	×	×	×		×	×	
6	8	×	×	×	×	×		×	×	
7	7	×	×	×	×	×		×	×	
8	7	×	×	×	×	×		×	×	
9	7	×	×	×	×	×		×	×	
10	7	—	—	×	×	×		×	×	
11	Died	×	×	×	×	×		—	—	
12	6	—	—	×	×	×		×	×	
13	6	×	×	×	×	×		×	×	
14	6	—	—	×	×	×		×	×	
15	5	—	—	×	×	×		×	0	
16	5	—	—	×	×	×		×	0	

0 = CT pending; Angio = angiography; IVUS = intravascular ultrasound; CT = computed tomography.

III, and 3 were grade IV. Maximum diameter of AAAs averaged 57 mm (range, 50–67 mm). Four patients had aneurysmal iliac arteries in addition to the AAAs that also were treated.

Prosthesis Design

The study evaluated the feasibility of deploying a self-expanding modular bifurcated endovascular prosthesis (Medtronic AneuRx, Inc, Cupertino, CA). The endoluminal prosthesis consists of self-expanding nitinol (nickel–titanium alloy) stents lined by a Dacron prosthesis (DuPont, Wilmington, DE). One component of the device is a bifurcated body with a 20-, 22-, 24-, 26-, or 28-mm diameter aortic segment and a corresponding 12-, 13-, 14-, 15-, or 16-mm diameter integral iliac limb. The bifurcated body also has a reinforced opening (pant-leg) for subsequent insertion of a contralateral 12-, 13-, 14-, 15-, or 16-mm diameter contralateral iliac limb component (Fig. 1).

Technique of Endoluminal Prosthesis Deployment

Procedures were performed in an endovascular interventional suite or an operating room, with the patients prepared and draped in a manner similar to preparation for conventional aortic surgery. General anesthesia was used for all procedures with an arterial line and Swan

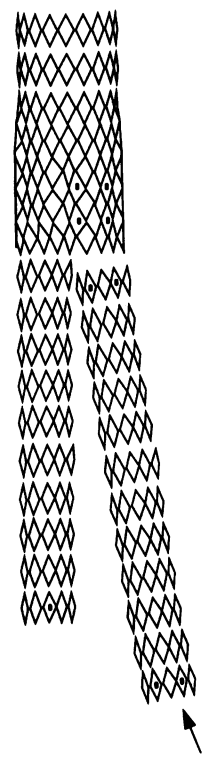

Figure 1. Diagram of the segmented nitinol (nickel–titanium alloy) stent superstructure of the endograft showing the bifurcated body and integral leg and the contralateral iliac limb component. The Dacron inner lining of the prosthesis is not shown.

Ganz catheter inserted for monitoring. Procedures were begun by making incisions over the femoral arteries to provide access for passage of the deployment catheters.

Before intervention, patients were anticoagulated with 100 units of heparin per kilogram and a 10-French hemostatic sheath was inserted through a puncture in the femoral artery that had been chosen by the preintervention evaluations as the best access route for the 21-French delivery component. The length of the aortoiliac access was crossed with a 0.035-in Glidewire (Medi-Tech, Inc, Natick, MA) and the Glidewire then was replaced with an angiographic catheter. A 0.025-in Platinum Plus guidewire (Medi-Tech) was inserted through the length of the angiographic catheter and the catheter removed. A 6.2-French, 12.5-mHz IVUS catheter was passed along the length of the wire to obtain IVUS images in the vascular segments being treated. The IVUS images were acquired using an HP Sonos IVUS imaging system (Hewlett–Packard Company, Andover, MA). Longitudinal gray scale and 3-D reconstruction of the axial IVUS images were acquired during timed catheter withdrawals with an IVUS image processing work station with analysis software (Interview, Quinton Instruments, Inc, Sunnyvale, CA). The location of relevant branch vessels, such as the hypogastric and renal arteries, was related to a radiopaque ruler that had been placed beneath the patient. Orifices were further identified with cinefluoroscopy imaging and compared to the location predicted by the IVUS catheter. Vessel location related to the ruler was determined at the center of the fluoroscopy image–screen to limit artifact caused by imaging parallax. Corresponding dimensions of the proximal and distal fixation sites for the endoluminal prosthesis in the infrarenal aorta and in the iliac limbs were determined with the IVUS. The length of the distance from the most inferior major renal artery to the aortic bifurcation and then to the hypogastric artery was determined by withdrawing the IVUS catheter from the proximal to the distal sites. The measurements of diameter and determination of the distances between the fixation sites were used to make final device selection. If the IVUS images did not confirm the appropriateness of the initial choice of aortoiliac vessels for inserting the 21F deployment catheter containing the main component of the prosthesis (chosen on the basis of preintervention images), then the contralateral iliac artery was interrogated using IVUS by repeating the methodology described. If the IVUS images confirmed the side for introduction of the main body that was chosen on the preintervention images, placement of the device proceeded. Before the deployment catheter was inserted, a limited angiogram was performed to confirm that the location of the arteries was identical to that determined by the IVUS so that precise deployment at the chosen site would be accomplished.

To deliver the main component of the endoluminal prosthesis, a 0.038 Amplatz Superstiff wire was introduced, and an arteriotomy in the femoral artery was made at the site of the guidewire entry to accommodate passage of the 21F outside diameter delivery catheter containing the aortoiliac component of the bifurcated Medtronic AneuRx device. The delivery catheter was passed over the wire to the infrarenal aortic position that had been chosen by IVUS and cineangiography. With the proximal end of the device in the appropriate location, deployment was performed. After removal of the delivery device, the guidewire was used to pass a Soft-Vu Omni Flush (SOS) catheter (AngioDynamics, Queensbury, NY), which was positioned at a point just above the renal arteries. A limited arteriogram was performed to confirm the location of the renal arteries referable to the cephalic end of the prosthesis and to observe for any evidence of a leak around the proximal end of the device.

The curved end of the SOS angiographic catheter then was positioned so that it looped over the flow divider in the bifurcated body of the Medtronic AneuRx device. A 0.025 angled glidewire then was passed through the angiographic catheter and around the bifurcation of the prosthesis and into the distal aspect of the aorta. At that point, the guidewire was advanced through the iliac artery into the contralateral groin and then retrieved through a small arteriotomy. In a few patients in whom the guidewire would not pass in the femoral artery using this method, the guidewire was captured using a 1-cm Amplatz snare that was introduced through a hemostatic sheath introduced through a puncture wound in the contralateral groin. After the wire in the contralateral groin was retrieved, it was withdrawn for a distance adequate to pass an angiographic catheter over the wire above the flow divider in the endoluminal device. The Glidewire then was withdrawn and a 0.038 Amplatz Superstiff wire placed to guide passage of the contralateral deployment catheter.

During the study, the technique for cannulating the opening in the body of the prosthesis for deployment of the contralateral limb of the prosthesis was changed. Passage of an original blunt-tipped design was difficult because the end of the catheter met resistance at or beneath the flow divider even when being passed over the Amplatz Superstiff wire. Beginning with the fifth patient treated, atraumatic insertion of the contralateral limb was accomplished by first passing an 18-French Desilet–Hoffman introducer sheath (Cook, Inc, Bloomington, IN) along the length of the iliofemoral artery and into the body of the device. After appropriate positioning of the contralateral limb to ensure firm fixation, deployment was accomplished and the catheter removed.

An angiogram of the length of the device then was performed through the SOS angiographic catheter that

had been maintained in a suprarenal position through the limb in the main body of the prosthesis. The SOS catheter then was used to pass a 0.025 Platinum Plus wire and the IVUS interrogation performed. The IVUS examinations were conducted to ensure firm fixation at the attachment points with confirmation of vessels as interpreted by the cineangiograms. Any abnormalities related to a questionable seal at the proximal or distal fixation sites or to constriction at any point along the prosthesis then were addressed by subsequent balloon dilation. In patients in whom balloon dilation was performed, completion cinefluoroscopy and IVUS then were repeated to confirm appropriate positioning and full expansion of the device.

Postprocedure Evaluation

At the completion of the procedures, blood that had been collected by an online autotransfusion device was reinfused into the patients. Patients were observed in the intensive care unit after the procedure with pulses and Doppler pressures in the affected extremities were documented and compared to measurements from the preintervention evaluation. Patients were permitted to have oral diet as tolerated the evening after the procedure and were begun on regular diet the next day. Patients were encouraged to ambulate and have activity to tolerance the day after the procedure. Contrast-enhanced spiral CT examinations were performed at 24 hours or at an interval when the CT scanner was available before patient discharge.

After discharge, the patients were re-evaluated at 1 month with a physical examination and duplex color flow scan and at 6 months with a contrast CT. The CT images were examined carefully to observe for changes in aortic diameters related to the device and to identify device migration. Follow-up visits included measurement of ankle brachial indices (ABIs), gathering information regarding the occurrence of new cardiovascular events, vascular status, and the patient's activity level compared to preintervention.

RESULTS

Sixteen patients (84% of those evaluated for entry into the study) met the entry criterion and were treated with a bifurcated prosthesis. All patients were treated successfully with no conversions to a conventional surgical procedure. Diameter of the aortic components of the devices deployed in this study was 20 mm in one, 22 mm in three, 24 mm in four, 26 mm in five, and 28 mm in three patients. In one patient (patient 2), the device would not deploy because of a malalignment of the stent segments when the prosthesis was loaded into the delivery catheter. The manufacturer corrected the problem and the patient was treated successfully during a second procedure. The success of intention to treat was thus 94%.

Table 3. COMPLICATIONS

Complication	Number (%)
Cardiac	0
Stroke, TIA	0
Pulmonary	
Prolonged intubation	1
Renal failure	
Transient (↑ Cr, BUN)	2
Arterial injuries	
Perforations	0
Dissections	2
Deaths	
Procedure related	1 (6)
Device related	0

TIA = transient ischemic attack; Cr = creatinine; BUN = blood urea nitrogen.

One procedure-related mortality occurred in a patient who died of septic complications secondary to a gangrenous gallbladder diagnosed 1 day after the procedure. There were no device-related mortalities. Complications included two iliac artery dissections, two groin wound infections, and two transient elevations of serum creatinine (Table 3). Other significant variables including median procedure length (5 hours), intensive care unit stay (1 day), hospitalization postprocedure (4.5 days), and blood loss (1100 mL) all decreased as the study progressed. Blood replacement in all but three patients was accomplished by autotransfusion or banked-autologous blood replacement.

No endoleaks or aneurysm enlargement was noted either acutely by contrast CT within 72 hours of the procedures or by duplex ultrasound examination at 1 month. At 6 months, 12 (92%) of 13 patients who were observed for this interval had no endoleaks, and 1 patient (patient 3) showed a small area of extravasation from the iliac limb below the flow divider in the main body of the device. Extensive evaluation of this patient suggests that the leak may be from a point in the device that was traumatized by multiple attempts to place the contralateral limb using methods that subsequently have been changed as detailed in the Methods section. Figure 2 shows sequential imaging of this patient that has been conducted to observe the leak. During the first 6 months of the study, the cross-sectional area of the site of maximal dilation has decreased by 44% (Table 4). Repeat imaging at 8 months to observe the leak showed persistence of a small area of extravasation on contrast CT and gadolinium magnetic resonance imaging, but there was no evidence of flow by color duplex. The maximal cross-sectional area

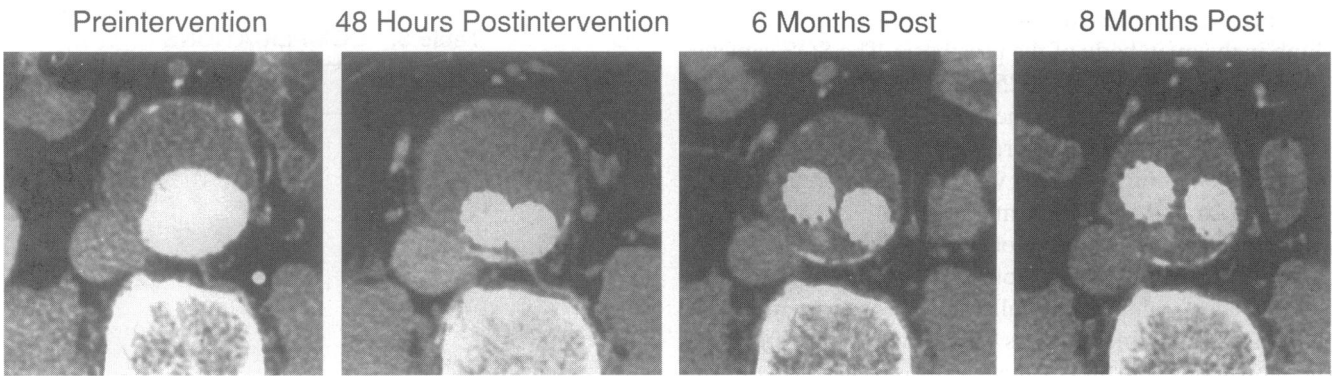

Figure 2. Sequential contrast computed tomography imaging of patient 3 showing the small area of contrast extravasation and the decrease in the size of the aneurysm. Also note the change in position (elevation and separation) of the limbs of the device that occurred with aneurysm shrinkage. This conformational change may be the reason for the appearance of the small leak at the site of prior trauma when no leak was originally seen.

and diameter of the aneurysm did not change between the 6- and 8-month evaluations.

Over the 6-month follow-up period in the first 13 patients, the maximum diameter of the aneurysm decreased on follow-up contrast CT examinations by an average of 5.6 mm (range, 0–15 mm), with the maximum cross-sectional area decreasing by 20.3% (range, 0–72%). There was near-complete regression of the aneurysm in one patient (Fig. 3), partial regression in nine patients, and no change in three patients. Regression appears to occur faster in patients with less thrombus in the aneurysm and less calcium in the aortic wall by CT evaluation, although this was not a uniform finding. Dimensions of the perirenal aorta immediately above the device did not change from preintervention dimensions in any patients, whereas the nonaneurysmal aortic and iliac segments containing the devices enlarged slightly to accommodate the maximum outside diameter of the self-expanding device. This occurred in nonaneurysmal, relatively normal arteries and in stenotic iliac arteries that had been dilated

Table 4. SIX-MONTH POSTPROCEDURE DATA

Patient Number	Postprocedure (mo)	Aortic Dimensions* (mm)		Change in Maximum Diameter (mm)†	Change in % Cross-sectional Area‡
		Preintervention	6 mo		
1	10	50 × 50	45 × 43	−5	−23
2	9	50 × 50	20 × 35	−15	−72
3	9	60 × 60	50 × 40	−10	−44
4	8	60 × 60	60 × 60	0	0
5	8	60 × 61	56 × 50	−4	−23
6	8	65 × 55	58 × 52	−7	−16
7	7	50 × 42	48 × 41	−2	−6
8	7	67 × 54	64 × 50	−3	−12
9	7	55 × 55	55 × 55	0	0
10	7	50 × 45	46 × 42	−4	−14
11	Died	—	—	—	—
12	6	70 × 50	58 × 46	−12	−24
13	6	52 × 45	52 × 45	0	0
14	6	53 × 45	42 × 40	−11	−30
15	5				
16	5				

* Longest and smallest diameters measured on axial CT images at the level of maximum aneurysm enlargement on preintervention study and at 6 month follow-up.
† Change in maximum diameter from preintervention and 6 month CT images at the level of maximum aneurysm enlargement.
‡ Change in cross-sectional from preintervention and 6 month CT images at the level of maximum aneurysm enlargement. Cross-sectional areas (CSA) were calculated using the formula: maximum radius × maximum radius × π (3.1416) = CSA.

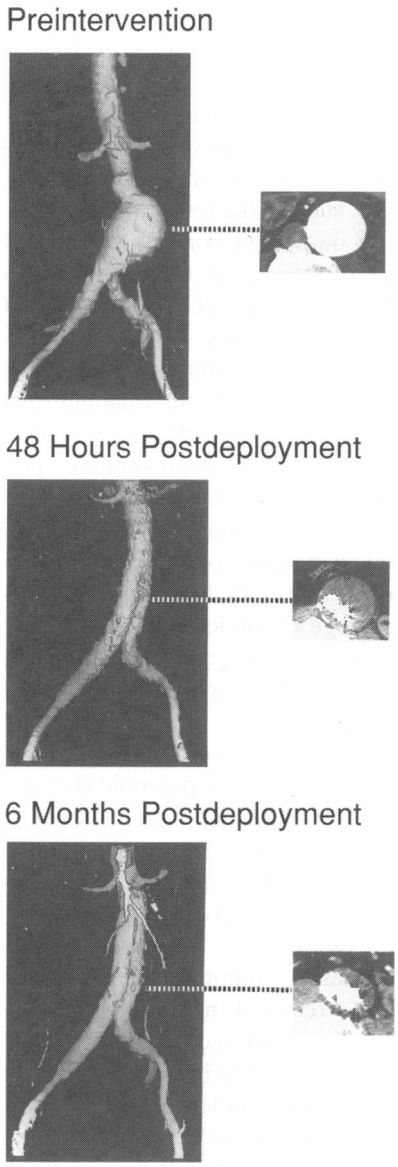

Figure 3. Computed tomography angiograms and cross-sectional axial views of an abdominal aortic aneurysm preintervention, at 48 hours postdeployment of a bifurcated Medtronic AneuRx device (Medtronic AneuRx, Inc, Cupertino, CA), and at 6 months postdeployment showing near-complete regression of the aneurysm.

during placement of the prostheses. There was no evidence of device migration in any patient. The location of the proximal end of the aortic component readjusted by 2 to 4 mm, referable to the renal arteries in two patients with angulated infrarenal aortic necks. The length and security of fixation did not change.

At follow-up examinations at 6 months, no new cardiovascular symptoms developed in any patients, and one patient (patient 7) was found to have metastatic lung cancer and died 1 month later. The ABIs performed on 13 patients at 6-month follow-up showed 15 limbs with ABI increased by >0.15 and 1 limb decreased >0.15 (1.5–0.95). The remainder of ABIs was unchanged from preintervention levels.

DISCUSSION

Endovascular exclusion of AAAs has been evaluated clinically for nearly 8 years using a variety of devices. Many of the reports in the literature describe experience that was developed using endografts fabricated by the investigator using a combination of available vascular prostheses and stents. Although the initial devices were difficult and time consuming to fabricate and deliver, the preliminary data showed that endovascular treatment of AAAs was technically possible with selective groups of patients potentially benefiting from further device development. This initial experience stimulated further development and refinement of several prototype devices that are now being investigated clinically in many countries throughout the world.

As part of this experience, potential benefits and complications that currently limit the scope of utility have been identified. The preliminary evaluation of an Endovascular Technologies, Inc (EVT, Menlo Park, CA) tube prosthesis suggested that this device may be applicable in 10% to 15% of patients with AAA with procedures being performed with acceptable morbidity and mortality.[6] Concerns regarding a persistent incidence of endoleaks have been reported with this device, although most have been sealed and persistent leaks have not caused problems in most patients in this initial group. Additional reports, including a recent study evaluating a significant percentage of high-risk patients using a modular bifurcated endoprosthesis fabricated by Mintec and Meadox Boston Scientific Corporation (Oakland, NJ) showed significant success with limited complications.[8] Many other series using a variety of developmental and investigator-fabricated devices report a spectrum of results. The identifiable limitations of endografts at the current time are being able to deliver devices by an endovascular means, identifying patients with adequate infrarenal and distal aortic or iliac artery fixation sites, and defining the implications of and the methods to prevent endoleaks. Many investigators are reporting that exclusion of the aneurysm prevents further growth and expansion with preliminary data, suggesting that regression at a progressive rate occurs.[6,9,11] Exclusion of the aneurysm without endoleaks has been shown to dramatically decrease pressure within the aneurysm and supports the assumption that exclusion of an aneurysm by an endovascular prosthesis can prevent delayed rupture.[12] Complete regression of an aneurysm has been reported and appears to have a potential to occur in patients with limited thrombus in the aneurysm and

minimal calcification in the aortic wall, as was encountered in one aneurysm that nearly regressed in this study.[13]

The methodology used in this study represents an attempt to address the issues of safe adaptability of this technology to a significant percentage of patients with AAAs. The imaging protocol that is outlined in this article was developed during a prior investigator Investigational Device Exemption (IDE) that evaluated the utility of various imaging methods, particularly contrast CT (axial and 3-D reconstructions) and IVUS as methods to enhance the appropriateness of patient selection for treatment with a custom-built, balloon-expandable endoluminal device.[7] The technical success during deployment and the follow-up evaluation of patients between 18 and 24 months treated in the previously published study showed long-term patency of repairs, a significant regression rate in some patients, and no incidence of endoleaks when IVUS was used as the primary method to size devices and to choose proximal and distal fixation areas. Although most investigations have been conducted using axial CT images and angiograms to size devices and determine patient candidacy, the high rate of endoleaks and reported incidence of dilation of proximal perirenal aortic segments may require an enhanced level of imaging precision, such as that offered by IVUS, to prevent these phenomena. It also may be that these complications will be unavoidable limitations of the technology, although the preliminary data using IVUS as the primary method to size devices and select deployment fixation areas are encouraging and await further evaluation.

In this study, we found that we were able to screen patients with uncomplicated anatomy based solely on axial CT images to determine approximate dimensions of the proximal and distal fixation sites and access vessels, and the 3-D spiral reconstructions for evaluating tortuosity and morphology of the aneurysm. In more complex patients with diseased access vessels and tortuous adjacent segments, preintervention angiography and IVUS interrogation was used to assess candidacy. In most situations, there was relatively good correlation between the aortic dimensions determined by IVUS and contrast CT, although the IVUS data frequently led to a change in the size of the device deployed compared to that chosen on the preintervention angiogram or CT data. In addition, we acquired significant data regarding the amount of distribution of atherosclerotic disease in the artery wall and relied on IVUS to determine the appropriate fixation sites to obtain a seal. The IVUS also increased the number of patients that could be treated by showing a short segment of common iliac artery proximal to the origin of the hypogastric artery that would accommodate and secure fixation of the distal limb of the device. These areas were not apparent on either accompanying cinefluoroscopy or preintervention CT images and enabled inclusion of these patients for treatment when they otherwise would not have been considered candidates by CT or angiographic imaging alone. Another advantage of the IVUS technology is that it limits the use of contrast dye to examinations that require either cinefluoroscopy confirmation of the ultrasound observations or confirmation of the patency of branch arteries, such as the renal and hypogastric arteries. By relying on outpatient contrast CT examinations for initial patient selection, we limited the use of invasive contrast angiogram and IVUS studies to patients with complex vessel morphology.

The complications encountered in this study included a prolonged intubation in the first patient treated. He had a history of pulmonary insufficiency, but this did not appear to be as severe as was encountered postprocedure. Two patients had a transient increase of the blood urea nitrogen and creatinine, although both of these occurred in patients who had evidence of compromised renal function preintervention. Two arterial dissections were created during the passage of guidewires and deployment catheters. Neither dissection required treatment beyond that accomplished with the deployment of the endoluminal device in the iliac arteries.

The procedure-related mortality deserves special consideration and highlights the potential risk, particularly in an ASA class IV patient like the patient who died in this study. This patient was known to have gallstones before the intervention, although there was no history consistent with cholecystitis. A gangrenous gallbladder on the day after the intervention was the only potential source of sepsis and systemic compromise that was found. This may have been a result of the prolonged procedure in this patient, which included reconstruction of the common femoral and profunda arteries in the left groin in which severe preexisting atherosclerotic outflow disease existed. The error in this patient was to underestimate the deleterious effect of a long anesthetic time caused by repairing this vessel as part of the procedure. Masking of intra-abdominal pathology will always be a potential liability of endoluminal and endoscopic procedures in which the peritoneal cavity is not fully explored. A shorter procedure and the avoidance of general anesthesia may have prevented this complication and may be averted in future interventions when the procedures will be performed in a more expedient manner using regional anesthesia.

In this study, we anesthestized patients using general anesthesia and placed a Swan–Ganz catheter and radial artery line for monitoring in the event that vessel perforation or another cause for conversion to aortobifemoral bypass was required. We also obligatorily placed patients in the intensive care unit for monitoring the first night after the procedure to avert any incidence of missed complications. In many institutions, investigators currently are placing endoluminal devices without Swan–Ganz or

radial artery hemodynamic monitoring and use regional anesthetics. The patients frequently are returned to the ward with more rapid initiation of ambulation and diet. In the future, we anticipate using more limited monitoring as the recovery in low-risk patients is shorter. For high-risk patients, intensive monitoring may continue to be indicated, although a less invasive approach may be used as improved techniques and devices evolve.

The endoleak that we have encountered in patient 3 at 6 months is puzzling because it appears to not be related to any of the frequently reported causes of endoleaks, such as lack of proximal or distal attachment site seals, leak from the contralateral attachment site in the bifurcated prosthesis, or from blood flow remaining within the aneurysm from a collateral vessel such as the inferior mesenteric or lumbar arteries. The origin of the leak has been identified carefully by contrast CT and magnetic resonance imaging and appears to originate from a point on the posterior medial aspect of the right limb of the device approximately 2 to 3 cm below the flow divider. A leak originating from this site is most likely due to trauma induced during the passage of the contralateral limb at a stage in the evolution of this procedure in which access was accomplished with some difficulty. Review of the images from the procedure, including a video of the introduction of the contralateral limb, indicates that excessive force may have been applied at this point during the placement of the contralateral limb. Although no leak was seen on the initial images at the time the patient was discharged, reorientation of the limbs, as shown in Figure 2, could have exposed a small tear or suture disruption to potentiate the leak. In this sense, the leak would be similar to those that have been reported recently in the Mintec and Boston Scientific devices that occurred at points in which fabric flaws were identified.[8] In this case, the external trauma might have produced an injury similar to a manufacturing defect. As a result of the difficult cannulations that occurred in the first few patients, the use of a Desilet–Hoffman introducer sheath (Cook, Inc) was adapted as described in the Methods section. This averted any other similar instances of difficult contralateral limb introduction and has led to a modification of the contralateral limb deployment catheter to avoid this situation. In this particular patient, we plan to continue observing the leak that has been noted and will monitor the aneurysm using duplex ultrasound and magnetic resonance at 2-month intervals until a repeat CT is to be performed at 1 year. To this point, his aneurysm has decreased from 60 × 60 mm to 50 × 40 mm at the point of maximal dilation. This represents a cross-sectional area reduction of 44% in the aneurysm over the first 6 months so that there appears to be no adverse affect of the minor extravasation that has been encountered. This decrease in aneurysm size is reassuring, although the implications of any endoleak are not yet known and we plan to continually monitor this patient to see if treatment by deployment of a small modular segment is required to seal the leak or if it will spontaneously close if the aneurysm continues to regress. Obviously, an additional question that remains unanswered is the eventual outcome of endografts placed in AAAs in which the thrombus does not eventually regress, although there have been no adverse events reported if the aneurysm sac remains isolated without endoleaks. This study suggests that exclusion of AAAs using the modular self-expanding device described may be effective in patients who are otherwise surgical candidates for repair if further clinical studies confirm these preliminary observations.

References

1. Parodi, JC, Palmaz JC, Barone HD. Transfemoral intraluminal graft implantation for abdominal aortic aneurysms. Ann Vasc Surg 1991; 5:491–499.
2. Parodi JC. Endovascular repair of abdominal aortic aneurysms and other arterial lesions. J Vasc Surg 1995; 21:549–557.
3. May J, White GH, Yu W, et al. Endoluminal grafting of abdominal aortic aneurysms: causes of failure and their prevention. J Endovasc Surg 1994; 1:44–52.
4. Marin ML, Veith FJ, Cynamon J, et al. Initial experience with transluminally placed endovascular grafts for treatment for complex vascular lesions. Ann Surg 1995; 222:449–469.
5. Chuter TAM, Donayre CE, White RA, eds. Endoluminal Vascular Prostheses. Boston: Little, Brown & Co.; 1995.
6. Moore WS, Rutherford RB. Transfemoral endovascular repair of abdominal aortic aneurysm: results of the North American EVT phase I trial. J Vasc Surg 1996; 23:543–553.
7. White, RA, Donayre CE, Walot I, et al. Preliminary clinical outcome and imaging criterion for endovascular prosthesis deployment in high-risk patients who have aortoiliac and traumatic arterial lesions. J Vasc Surg 1996; 24:556–571.
8. Blum U, Voshage G, Lammer J, et al. Endoluminal stent-graft for infrarenal abdominal aortic aneurysms. N Engl J Med 1997; 336:13–20.
9. Matsumura JS, Pearce WH, McCarthy W, Yas JST. Reduction in aortic aneurysm size: early results after endovascular graft placement. J Vasc Surg 1997; 25:113–123.
10. White RA, Fogarty TJ, Kopchok GE, et al. Evaluation of a modular endovascular bifurcation prosthesis in a canine aortic aneurysm model. J Vasc Surg 1996; 24:1034–1042.
11. May J, White G, Yu W, et al. A prospective study of anatomicopathological changes in abdominal aortic aneurysms following endoluminal repair: is the aneurysmal process reversed? E J Vasc Endovasc Surg 1996; 12:11–17.
12. Chuter T, Ivancev K, Malina M, et al. Aneurysm pressure following endovascular exclusion. E J Vasc Endovasc Surg 1997; 13:85–87.
13. White RA, Donayre CE, Walot I, et al. Regression of an abdominal aortic aneurysm following endograft exclusion. J Vasc Surg 1997; 26:133–137.

Discussion

DR. ANTHONY D. WHITTEMORE (Boston, Massachusetts): We are all saddened that Dr. Rodney White could not be with us